PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant:	Ruchika Singhal	Confirmation No.	6514
Serial No.:	10/691,917		
Filed:	October 23, 2003	Customer No.:	28863
Examiner:	Michael William Kahelin		
Group Art Unit:	3762		
Docket No.:	1023-234US01		
Title:	AUTOMATIC THERAPY ADJUSTMENTS		

CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via the United States Patent and Trademark Office electronic filing system on April 22, 2011.

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REPLY BRIEF

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Commissioner for Patents
Alexandria, VA 22313-1450

Dear Sir:

This is a Reply Brief responsive to the Examiner's Answer mailed on February 22, 2011 (hereinafter "Examiner's Answer"), which was responsive to Appellant's Appeal Brief filed on May 21, 2010. The due date for this Reply Brief is April 22, 2011.

No fees are believed to be due at this time. Please charge any fees that may be required or credit any overpayment to Deposit Account No. 50-1778.

TABLE OF CONTENTS

STATUS OF CLAIMS

Claims 1, 5–19, 23–38, and 42–56 are pending and are the subject of this Appeal. Claims 1, 5–19, 23–38, and 42–46 are set forth in Appendix A of the Appeal Brief filed May 21, 2010. Claims 49–54 were added by way of an Amendment filed on July 14, 2006. Claims 2–4, 20–22, and 39–41 were cancelled and claims 55 and 56 were added in an Amendment accompanying a Request for Continued Examination (RCE) filed on March 12, 2007.

Claims 1, 5–19, 23–38, and 42–56 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The ground of rejection to be reviewed on appeal is:

the rejection of claims 1, 5–19, 23–38, and 42–56 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

REMARKS

In the Examiner's Answer to the Appeal Brief, the Examiner provided additional comments regarding the supposed basis of the rejection of Appellant's claims. In particular, on page 4 of the Examiner's Answer, the Examiner stated: "[t]he Examiner was unable to find support in the originally-filed application for the amended claim limitation of monitoring the therapy 'while the output of the sensor was monitored.'" With respect to claims 1, 5–18, 48, 50, and 55, on pages 4 and 5, the Examiner's Answer stated:

> The examiner's rejection is premised on the following elements: (i) the disputed new claim limitation requires simultaneous "monitoring of therapy" (*e.g.*, monitoring stimulation parameters applied to a patient) and "initially defining an event" (*e.g.*, recording a sensor output and defining that output to correspond to sitting, running, standing, etc.); (ii) the originally filed disclosure describes "monitoring a therapy" during a "learning mode"; (iii) the originally filed disclosure describes "initially defining an event" during a "learning mode"; (iv) the originally-filed disclosure lacks description of "monitoring a therapy" and "initially defining an event" at the same time during the "learning mode" (see, *e.g.*, Figure 5's disclosure of these steps being performed in sequence/serially and not simultaneously) (emphasis in original).

With respect to claims 1, 5–18, 49, 50, and 55, the Examiner's Answer also referred to an analogy provided in the Advisory Action dated March 12, 2010. In particular, the Examiner's Answer, on page 6, stated: "[a]s indicated in the Advisory Action of 3/12/2010, please consider the following analogy: disclosure of eating breakfast in the morning and getting dressed in the morning does not support the more specific case of eating breakfast while getting dressed." The Examiner's Answer, on page 6, concluded that "[l]ikewise, Appellant's disclosure that both events occur during some 'mode' or period of time does not support the concept that both 'defining' and 'monitoring' occur simultaneously."

On this basis, the Examiner's Answer maintained the rejection under 35 U.S.C. § 112, first paragraph of claims 1, 5–18, 49, 50, and 55. With respect to claims, 19, 23–37, 51, and 52, claims 38, 42–48, 53, and 54, and claim 56, the Examiner's Answer, on page 6, stated that "[s]imilar comments apply to the similar claim limitations, as addressed above. In Appellant's Appeal Brief, Appellant separately argued claims 1, 5–18, 49, 50, and 55, claims 19, 23–37, 51, and 52, claims 38, 42–48, 53, and 54, and claim 56, and respectfully requested separate review by the Board for each set of claims argued under separate headings. Although the Examiner's

Answer asserted that similar comments apply to similar claim limitations, Appellant respectfully maintains that the Board should separately review each set of claims argued under separate headings.

CLAIMS 1, 5–18, 49, 50, AND 55

The rejections under 35 U.S.C. § 112, first paragraph, of claims 1, 5–18, 49, 50, and 55 are improper. For example, the Examiner asserted that Appellant's FIG. 5 illustrates that the monitoring the output of the sensor and monitoring therapy delivered by the medical device occur sequentially. However, the example illustrated in Appellant's FIG. 5 is not the only example provided in Appellant's disclosure. Indeed, when one of ordinary skill in the art considers Appellant's disclosure in its entirety, Appellant submits that one of ordinary skill in the art would have recognized that Appellant possessed the feature "monitoring therapy delivered by a medical device while the output of the sensor was monitored during the event to initially define the event," as set forth in claim 1.

For instance, paragraph **[0056]** of Appellant's disclosure, which describes FIG. 5 of Appellant's disclosure states: "FIG. 5 is a flow diagram illustrating an exemplary operation of IMD 12 according to a learning mode." Paragraph **[0061]** of Appellant's disclosure, which describes FIG. 6 of Appellant's disclosure states: "FIG. 6 is a flow diagram illustrating **another** exemplary operation [of] IMD 12 according to a learning mode (emphasis added)." One of ordinary skill in the art would have recognized that the term "another" in the above-recited sentence of paragraph **[0061]** clearly indicates that the learning mode example of FIG. 6, in Appellant's disclosure, describes a learning mode example that may be different than the learning mode example illustrated in FIG. 5 of Appellant's disclosure.

Paragraph **[0062]** of Appellant's disclosure, which Appellant cited as providing at least implicit support for the features of claim 1 in Appellant's Appeal Brief, further describes the example of FIG. 6 of Appellant's disclosure. Paragraph **[0062]** states that "[p]rocessor 34 may record the sensor output or information over any length of time, may record multiple samples, and may make the recording or recordings at any time after entering the learning mode." (Emphasis added). Paragraph **[0062]** of Appellant's disclosure further states that "[p]rocessor 34 may store the recording(s), or the result of an analysis, e.g. feature, Fourier, or wavelet, or the recording(s) in memory 36 as an event 52. Processor 34 records therapy information as a learned

therapy 54 during operation in the learning mode (84), and associates the learned therapy 54 with the defined event 52 (86), as described above with reference to FIG. 5." (Emphasis added).

Given that one of ordinary skill in the art, for the reasons above, would have recognized that FIG. 6 of Appellant's disclosure describes an example that may be different than that of FIG. 5 of Appellant's disclosure, one of ordinary skill in the art would have recognized that in the example of FIG. 6 of Appellant's disclosure, monitoring therapy delivered by a medical device need not necessarily occur after monitoring an output of the sensor. For example, if FIG. 5 of Appellant's disclosure describes monitoring therapy after monitoring the output of the sensor in the learning mode, and FIG. 6 describes another example of operation in the learning mode, then one of ordinary skill in the art would have recognized that Appellant's disclosure is not limited to monitoring the output of the sensor, and then monitoring therapy delivered by the medical device.

Indeed, upon reference to Appellant's disclosure, for example, paragraph **[0062]**, one of ordinary skill in the art would have recognized that Appellant possessed more than the sequential monitoring of output and therapy, and in particular at least parallel monitoring of output and therapy. For example, paragraph **[0062]** of Appellant's disclosure makes clear that monitoring the output of the sensor and monitoring of delivered therapy occur during "any length of time" within the learning mode. If monitoring of the sensor output can occur any time and over any length time in the learning mode, and monitoring of the delivered therapy occurs in the learning mode, then, at least implicitly, paragraph **[0062]** supports monitoring therapy delivered by a medical device while the output of the sensor was monitored. Accordingly, paragraph **[0062]** demonstrates that Appellant possessed the claimed feature of "monitoring therapy delivered by a medical device while the output of the sensor was monitored during the event to initially define the event," recited in claim 1.

Moreover, the Examiner's eating breakfast in the morning and getting dressed in the morning analogy is helpful in understanding the Examiner's position. However, this analogy fails to recognize what one of ordinary skill in the art would have considered Appellant as possessing at the time of filing. A determination of whether the written description requirement is met is based on the knowledge of one of skill in the art. [1] Appellant respectfully submits that

[1] *See* MPEP 2163(II)(A) which states: "[t]he analysis of whether the specification complies with written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine

one of ordinary skill in the art, upon referencing paragraph **[0062]**, as well as, the entirety of the specification, would recognize that Appellant possessed the features of the claims.

As described in Appellant's Appeal Brief, paragraph **[0035]** states: "[p]atient 14 may...simply begin running and allow IMD 12 to record an exemplar of the sensor output while patient 14 is running...[w]hile patient 14 is running...patient 14 uses programming device 20, e.g., keypad 24, to change one or more stimulation parameters in an attempt to maintain adequate symptom control during the activity." Paragraph **[0059]** states: "patient 14 adjusts stimulation parameters over a period of time after directing IMD 12 to enter the learning mode, e.g., during the event...so that IMD 12 learns appropriate adjustments to therapy to provide while patient 14 is running, and may adjust stimulation parameters while running to maintain effective and comfortable neurostimulation therapy." (Emphasis added). Paragraph **[0066]** goes on to state: "[f]or example, an event 52 may be patient 14 running, and the learned therapy 54 may include changes to stimulation parameters occurring at associated times during the "running" event such that effective and comfortable therapy is maintained."

Initially defining the event comprises monitoring the sensor output for some period of time, and storing an indication of the monitored sensor output during that period of time as the defined event. It is clear from the cited paragraphs that the monitoring of the therapy may occur during the event, i.e., during the period of time in which the sensor output was monitored, so that an IMD or other device learns appropriate adjustments to therapy to provide during the event (when subsequently detected) to maintain effective and comfortable neurostimulation therapy.

Moreover, one of ordinary skill in the art would have read Appellant's specification to disclose that, in at least one example, monitoring therapy delivered by a medical device would occur while the output of the sensor was monitored to provide some possible, non-limiting advantages. For example, paragraph **[0011]** describes that a possible advantage is to provide a medical device that can "provide therapy that better addresses changes in the symptoms of a patient and/or level of efficacy or side effects of the therapy associated with an activity undertaken by the patient." (Emphasis added). One of ordinary skill in the art would understand that monitoring for therapy changes during the definition of the event, rather than after the event

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whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed."

had been defined and may have ended, would have facilitated addressing changes in symptoms during a subsequent occurrence of the event.

For at least all the reasons advanced above, Appellant's disclosure conveys to one of ordinary skill in the art that the inventor(s) possessed the claimed invention at the time of filing. Appellant respectfully requests reversal of the rejections under 35 U.S.C. § 112, first paragraph for claim 1. Claims 5–18, 49, 50, and 55 depend upon claim 1. Since the 35 U.S.C. § 112, first paragraph rejection is improper for claim 1, the 35 U.S.C. § 112, first paragraph rejection for claims 5–18, 49, 50, and 55 is improper. Appellant respectfully requests withdrawal of the rejections under 35 U.S.C. § 112, first paragraph for claims 5–18, 49, 50, and 55.

CLAIMS 19, 23–37, 51, AND 52

The rejections under 35 U.S.C. § 112, first paragraph, of claims 19, 23–37, 51, and 52 are improper. For example, as described above, paragraphs **[0062]**, **[0035]**, **[0059]**, **[0066]**, and **[0011]** of Appellant's disclosure provide support for a processor that "monitors therapy delivered by the therapy delivery module device while the output of the sensor was monitored during the event to initially define the event," as set forth in claim 19.

For example, paragraph **[0062]** of Appellant's disclosure describes an example that may be different than the example of FIG. 5 of Appellant's disclosure. In the example described in paragraph **[0062]**, a processor monitors the output of the sensor over any length of time in the learning mode, and the processor monitors therapy during the learning mode. Therefore, while FIG. 5 of Appellant's disclosure describes one example where the monitoring of the output and the monitoring of the therapy occur sequentially, paragraph **[0062]** of Appellant's disclosure describes an example where monitoring of the sensor and monitoring of the therapy do not occur sequentially. Rather, paragraph **[0062]** of Appellant's disclosure describes that such monitoring of the therapy may occur at the same time, or at least overlapped in time, with the monitoring of the sensor output.

For at least all the reasons advanced above, Appellant's disclosure conveys to one of ordinary skill in the art that the inventor(s) possessed the claimed invention at the time of filing. Appellant respectfully requests reversal of the rejections under 35 U.S.C. § 112, first paragraph for claim 19. Claims 23–37, 51, and 52 depend upon claim 19. Since the 35 U.S.C. § 112, first paragraph rejection is improper for claim 19, the 35 U.S.C. § 112, first paragraph rejection for

claims 23–37, 51, and 52 is improper. Appellant respectfully requests withdrawal of the rejections under 35 U.S.C. § 112, first paragraph for claims 23–37, 51, and 52.

CLAIMS 38, 42–48, 53, AND 54

The rejections under 35 U.S.C. § 112, first paragraph, of claims 38, 42–48, 53, and 54 are improper. For example paragraphs **[0062]**, **[0035]**, **[0059]**, **[0066]**, and **[0011]** of Appellant's disclosure provide support for a computer-readable medium comprising instructions that cause a programmable processor to "monitor therapy delivered by a medical device while the output of the sensor was monitored during the event to initially define the event," as set forth in claim 38.

For example, in the example described in paragraph **[0062]**, which describes an example that may be different than the example of FIG. 5 of Appellant's disclosure, a processor monitors the output of the sensor over any length of time in the learning mode, and the processor monitors therapy during the learning mode. The example of FIG. 5 of Appellant's disclosure describes one non-limiting example where the monitoring of the sensor output and the monitoring of the therapy occur sequentially in the learning mode. The example described in paragraph **[0062]** describes another example, where the monitoring of the sensor output and the monitoring of the therapy do not necessarily occur sequentially. Rather, such monitoring may occur over any length of time during the learning mode. Based on the entirety of Appellant's disclosure, Appellant respectfully submits that one of ordinary skill in the art would have read Appellant's disclosure in such a manner that the computer-readable medium comprises instructions that cause the programmable processor to monitor therapy delivered by a medical device, at the same time, or at least overlapped in time, while the output of the sensor was monitored during the event to initially define the event.

For at least all the reasons advanced above, Appellant's disclosure conveys to one of ordinary skill in the art that the inventor(s) possessed the claimed invention at the time of filing. Appellant respectfully requests reversal of the rejections under 35 U.S.C. § 112, first paragraph for claim 38. Claims 42–48, 53, and 54 depend upon claim 38. Since the 35 U.S.C. § 112, first paragraph rejection is improper for claim 38, the 35 U.S.C. § 112, first paragraph rejection for claims 42–48, 53, and 54 is improper. Appellant respectfully requests withdrawal of the rejections under 35 U.S.C. § 112, first paragraph for claims 42–48, 53, and 54.

CLAIM 56

The rejection under 35 U.S.C. § 112, first paragraph, of claim 56 is improper. As described above, paragraphs **[0062]**, **[0035]**, **[0059]**, **[0066]**, and **[0011]** when taken either alone or together, clearly demonstrate that Appellant possessed the feature of "monitoring therapy delivered by a medical device while the output of the sensor was monitoring during the event to initially define the event," as set forth in claim 56. Appellant respectfully submits that one of ordinary skill in the art would have read Appellant's disclosure in such a manner that monitoring therapy delivered by a medical device occurred at the same time, or at least overlapped in time, while the output of the sensor was monitored during the event to initially define the event, as set forth in claim 56.

For at least all the reasons advanced above, Appellant's disclosure conveys to one of ordinary skill in the art that the inventor(s) possessed the claimed invention at the time of filing. Appellant respectfully requests reversal of the rejections under 35 U.S.C. § 112, first paragraph for claim 56.

CONCLUSION

For at least these reasons and the reasons discussed in Appellant's Appeal Brief, the Examiner has failed to meet the burden of establishing a *prima facie* case of nonpatentability with respect to Appellant's claims 1, 5–19, 23–38, and 42–56. In view of Appellant's arguments present in this Reply Brief and in the previously-filed Appeal Brief, the final rejection of Appellant's claims was improper and should be reversed. Reversal of all pending rejections and allowance of all pending claims is respectfully requested.

Date: April 22, 2011

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